

REMARKS

In the final Office Action dated June 4, 2001, it is indicated that claims 22 - 58 are pending. Applicants emphasize that non-elected claims 28 - 40, 43 - 45 and 49 were canceled in the amendment dated March 27, 2001. Claims 22 - 27, 41, 42, 46 - 48 and 50 - 58 are pending in the instant application. Claim 57 has been rewritten in independent form to explicitly incorporate the limitations of claim 22. Applicants contend the instant amendment places the claims in form for allowance, does not raise new issues, and reduces the issues for appeal.

The pending claims are rejected under 35 U.S.C. §102(b) as being anticipated by Oshlack et al., (U.S. Pat. No. 5,639,476) and under 35 U.S.C. §103(a) as being unpatentable over Oshlack et al., (U.S. Pat. No. 5,639,476). There are no other rejections in the application.

With respect to the rejection under 35 U.S.C. §102(b) the Examiner states,

"Oshlack teaches a pharmaceutical formulation in the form of tablets, beads, seeds or granules that can be coated with a coating composition comprising water-insoluble hydrophobic polymer (column 5, lines 56 - 67; and column 7, lines 35 through column 8, lines 1 - 19), water-soluble hydrophilic polymers (column 10, lines 45 - 60), modified starch (column 11, lines 12 - 41), and plasticizer (column 12, lines 29 through column 14, lines 1 - 40)."

In order for a reference to anticipate, the reference must clearly and unequivocally disclose the claimed invention such that the reference sufficiently describes the claimed invention to have placed the public in possession of it. Applicants assert the Oshlack et al. reference fails this test.

As previously discussed, Oshlack et al. is directed to a stable solid controlled release formulation coated with an aqueous dispersion of a hydrophobic acrylic polymer, particularly an aqueous dispersion of plasticized acrylic polymer. (See column 7, lines 35 - 38). The reference further discloses that the hydrophobic acrylic polymer coating may include other components such as: (1) Other monomers, such as styrene and its homologs, vinyl esters, such as vinyl acetate, and vinyl chloride, acrylamide, methacrylamide, hydroxy alkyl esters of acrylic acid and methacrylic acid and vinyl pyrrolidone (See column 7, lines 56 - 63 and column 9, lines 63 - 67). (2) One or more polymerizable permeability enhancing compounds, including at least one polymerizable

quaternary ammonium compound. These compounds are strong bases, and particular examples of quaternary ammonium compounds are listed in column 8, lines 30 – 67 and column 9, lines 1 – 8 of the reference. (3) A long laundry list of pore forming polymers such as hydroxypropylmethylcellulose; cellulose ethers such as hydroxyalkylcelluloses and carboxyalkylcelluloses; protein derived materials; polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone, saccharides and polysaccharides, such as pullulan, dextran, sucrose, glucose, fructose, mannitol, lactose, sorbitol, alkali metal salts, polymers such as Carbowax®, starch, modified starch and starch derivatives, gums, ion-exchange resins, polycarbonates and others (See column 10, lines 45 – 67 and column 11, lines 1 – 41). (4) Plasticizing agents for the acrylic coating and particularly citric acid esters (See column 12, lines 29 – 60 and column 13, lines 1 – 25).

In a preferred embodiment the Oshlack et al. coating is directed to copolymerizates of acrylic and methacrylic acid esters with a low content of quaternary ammonium groups and a further material selected from the group of polymerizable permeability enhancing agents, water-soluble acrylic polymers, pore-formers and mixtures thereof.

Applicants' invention is directed to a coating comprising a plasticizer, modified starch, and modified cellulose, wherein the modified starch and modified cellulose are provided in equal parts. Clearly there is no teaching in Oshlack et al. directed to this coating. Moreover, Applicants contend the reference does not teach one skilled in the art a coating comprising a modified starch, a modified cellulose and a plasticizer. Oshlack et al. includes an aqueous dispersion of a water insoluble polymer and in certain preferred embodiments the acrylic polymer includes one or more polymerizable permeability-enhancing compounds which will allow the active agent enclosed in the coating to be released at a desired which rate. The diffusion rate may be further influenced by pore formers. Oshlack et al. state that useful pore formers include both starch and modified starch. Applicants specifically teach at page 3, that unmodified starch or cellulose is not a good coating material. Additionally at page 3, it is taught that modified starch on its own is not, in general a good coating material.

With respect to the rejection under 35 U.S.C. §103(a) the Examiner states,

"Oshlack is relied upon for the reasons stated above. Regarding to claim 42, Oshlack is silent as to the disclosing of enzyme. However, Oshlack teaches a cleansing agent including deodorant,

surfactant, germicide, and sanitizer. Hence it would have been *prima facie* obvious for one of ordinary skill in this art to, by routine experimentation determine suitable cleansing agent including enzyme. The reason for this modification is to obtain a stable coated composition that is useful in the pharmaceutical and cosmetic arts."

Applicants submit the cited reference neither discloses or provides any motivation to make the claimed coating. It is impermissible within the framework of section 103 to pick and choose from any reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. Beyond looking at the cited prior art to determine if it suggests doing what the inventor has done, one must also consider if the cited art provides the required expectation of success. (In re Dow Chemical 473 USPQ2d 1529 (Fed. Cir 1988). Both the suggestion and the expectation of success must be founded in the cited prior art and not in Applicants' disclosure. Applicants assert the Oshlack et al. reference is deficient on both accounts, and that a *prima facie* case of obvious has not been made.

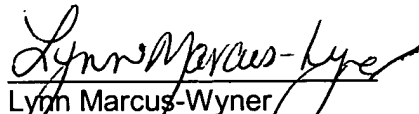
While it is true that the hydrophobic acrylic polymer coatings of the reference may be used to coat substrates such as tablets, beads, microspheres, seeds, pellets, and the like, the coating of the instant invention is different and non-obvious from the reference's disclosure, and therefore substrates including the claimed coating are also unobvious.

Applicants respectfully request that the rejections over Oshlack et al. be withdrawn. Pending claims 22 - 27, 41, 42, 45 - 48 and 50 - 58 are in form for allowance, and allowance of the application is kindly solicited.

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MARKED-UP VERSION OF THE PENDING CLAIMS

57(Once amended) [The coating of claim 22] A coating comprising,
(i) a modified starch wherein the modification includes ethylation, acetylation,
methylation, hydroxypropyl substitution, hydroxyethyl substitution,
carboxymethyl substitution or hydroxypropyl methyl substitution; (ii) a
plasticizer; and (iii) a modified cellulose as a secondary polymer, wherein the
modified starch and the secondary polymer are provided in equal parts.